

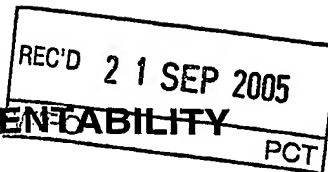
# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference <b>PREP07224WO</b>	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. <b>PCT/GB2004/002606</b>	International filing date (day/month/year) <b>18.06.2004</b>	Priority date (day/month/year) <b>10.07.2003</b>	
International Patent Classification (IPC) or national classification and IPC <b>C07F7/08, A61K31/695, A61P31/00, A61P9/00, A61P35/00, A61P5/00</b>			
Applicant <b>AMEDIS PHARMACEUTICALS LTD.</b>			
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 4 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).			
4. This report contains indications relating to the following items: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion  <input type="checkbox"/> Box No. II Priority  <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  <input type="checkbox"/> Box No. IV Lack of unity of invention  <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  <input type="checkbox"/> Box No. VI Certain documents cited  <input type="checkbox"/> Box No. VII Certain defects in the international application  <input type="checkbox"/> Box No. VIII Certain observations on the international application                 </div>			
Date of submission of the demand  <b>02.02.2005</b>	Date of completion of this report  <b>22.09.2005</b>		
Name and mailing address of the international preliminary examining authority:  <div style="display: flex; align-items: center;"> <div>                         European Patent Office - P.B. 5818 Patentlaan 2                          NL-2280 HV Rijswijk - Pays Bas                          Tel. +31 70 340 - 2040 Tx: 31 651 epo nl                          Fax: +31 70 340 - 3016                     </div> </div>	Authorized Officer  <b>Rinkel, L</b>  Telephone No. +31 70 340-2834		



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/002606

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-33 as originally filed

**Claims, Numbers**

1-28 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-28
	No: Claims	
Inventive step (IS)	Yes: Claims	1-28
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-28
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following document:

D1: WO 00/20358 A , cited in the application

2. The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows compounds comprising a tetrahydronaphthalene moiety, and their therapeutic use.

The subject-matter of claim 1 differs from these known compounds, in that a silicon-substituted phenyl rings replaces the tetrahydronaphthalene moiety.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

3. With the demonstrated activity of the presently claimed compounds, the problem underlying the present invention could be seen as the provision of further compounds with GnRH activity. The presently claimed compounds are considered structurally and chemically remote from the prior art compounds. As there appear to be no teachings in the available prior art that would allow a person skilled in the art to modify the teachings of D1 so as to arrive at the present solution, the present application is considered to involve an inventive step (Article 33(3) PCT).

Claims 2-28 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.